REMARKS

Claims 11-25, 27-32, 35-49 and 51-59 remain in the application for further prosecution. Claims 12, 20, 25, 28, 36, 38, 47 and 53-57 have been amended above and Claim 33 cancelled.

I. Rejections Under 35 U.S.C. § 112

Claims 11-21, 27-33, 35-49, and 51-56 were rejected under 35 U.S.C. § 112. More specifically, the Examiner objected to use of the term "substantially" or "substantially removed" in connection with the degree to which the native oxide layer is removed or the roughness of the final surface. The Examiner takes the position that the specification fails to provide some standard by which the roughness of the surface or the degree of removal of the oxide surface could be determined when the term "substantially" is used. Reconsideration is again requested. No standard can be established in the present invention because including the word "substantially" is consistent with the appearance of the surfaces shown in the photomicrographs. A precise description of the surfaces, when magnified at 2000 X, is not possible. Furthermore, as discussed in *Andrew Corporation vs. Gabriel Electronics, Inc.*, 6 U.S.P.Q.2d, 2010, it will be understood by those skilled in the art that this use of the words "substantially" and "substantially removed" are appropriate in the present context. The Andrew opinion cites several earlier decisions that support the Applicant's belief that the present claims are as precise as the present subject matter permits.

For the surface of implants to be roughened as uniformly as possible, the native oxide is removed before acid etching. It is evident from the photomicrographs that words cannot describe the topography of the surface without qualifying expressions. This follows also from the methods used in which acids are used to remove native oxide and to roughen the surface. The Applicants want to describe their implants as accurately as possible, but without being

unduly limiting. If the Examiner believes that other language would adequately cover the roughened surfaces shown in the application, the Applicant will consider his suggestions.

In Claims 12, 20, 25, 28, 38, 47, 53, 54, 55 and 56 the word "substantially" has been deleted in connection with the number of irregularities and the shape of the elements. The Applicants believe that those usages of the word "substantially" are appropriate, but the word has been deleted to advance prosecution.

II. Rejections Based On Krueger

Claims 11-16, 22-25, 27-33, 35-49 and 54-56, were rejected under 35 U.S.C. § 102(b) as anticipated by Krueger or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Krueger alone. The Examiner asserted that at least one of the intermediate or final product of Kreuger would have the native oxide layer removed and would have irregularities of less than 10 microns.

The text of the Krueger patent is too vague, however, to support such a conclusion. Krueger says only that the etching techniques correspond to those used in etching the electrodes of electrolytic capacitors, but are not set forth in detail. This disclosure could not enable one skilled in the art to understand or duplicate the methods used by Krueger. Therefore, the Applicants contend that the Krueger reference does not anticipate, since a reference cannot anticipate when it does not enable, MPEP 2121. The Examiner has suggested that the Applicants duplicate Krueger to etch with mineral acid to an etch ratio greater than two. In response, a series of tests has been carried out, which are reported in the attached declaration under 37 C.F.R. 1.132 by Dr. Prabhu Gubbi. The Examiner is asked to carefully review the results of tests of various mineral acids on titanium surfaces (Exhibit C) and on titanium surfaces that had been previously grit-blasted (Exhibit D). Dr. Gubbi found that none of the titanium

surfaces had a roughness twice the initial value, nor did any of the surfaces resemble the surface of the implants described in the present application. Thus, it is clear that Krueger's disclosure provides no basis for one skilled in the art to make the implants of the invention.

Claims 51-53 were rejected under 35 USC 103(a) as unpatentable over Krueger in view of Niznick. Krueger was applied as above to Claims 11-16, 22-25, and 27-49. The deficiencies of Krueger have been made clear in the previous discussion and by the tests reported in Dr. Gubbi's declaration. Niznick was cited for the use of different regions of roughness on implants. In fact, Niznick teaches the advantages of having relatively smooth distal and proximal end portions, while the middle portion has a greater surface roughness. Combining Niznick with Krueger does not make the present claims obvious and unpatentable. Also, while Niznick does refer to the advantages of a relatively smooth neck portion of an implant he provides no basis for concluding that the roughened region should begin about 3 mm below the top surface.

III. Rejections Based on Haruyuki et al.

Claims 11-16, 22-25, 27-33, 35-49, and 54-59 were rejected under 35 USC 103(a) as unpatentable over Haruyuki et al. (Haruyuki) in view of Krueger. Haruyuki was cited for disclosing an acid-etched titanium implant. Krueger was cited for teaching threaded implants.

The English translation of the Haruyuki patent teaches a method of treating the surface of a titanium implant with a solution of hydrofluoric acid, which is then followed by post-treatment with a solution of hydrofluoric acid and hydrogen peroxide. The initial treatment with a solution of 1-6 wt % HF for 30 seconds to 3 minutes is said to create pits which have sharp edges. Then, the post-treatment is performed to smooth the sharp edges, which can cause tissue irritation (Translation, page 4, left column). Thus, Haruyuki does not teach a second treatment that roughens the surface from which the native oxide had been removed. To the contrary, Haruyuki

teaches smoothing the sharp edges produced by the first treatment. In fact, in the declaration by Dr. Gubbi the tests set forth in Haruyuki were repeated and the results (Exhibit B) confirmed the smoothing performed by the post-treatment.

The Applicant's preferred process employs a solution of hydrofluoric acid more concentrated than Haruyuki to remove the native oxide. This would not be acceptable to Haruyuki because he teaches that more concentrated acid creates pits that are too deep with sharp edges (Translation, page 4). Again, Haruyuki's second step was intended to smooth the sharp edges created by his first treatment with hydrofluoric acid, rather than to further roughen the surface.

Since the photographs in the Haruyuki application were not clear, copies have been obtained from the application in the Japanese Patent Office. From these photographs, attached as Exhibit 1, it is clear that the surfaces have a different topography from the Applicant's surface, perhaps due to the fact that the Applicant further roughens the surface after the native oxide is removed, while Haruyuki smooths the surface created in their first step. To further compare Haruyuki's results with the Applicant's results, the Applicant has had the experiments reported by Haruyuki repeated. The Applicant's surface (*i.e.*, the Osseotite® surface) is shown in Exhibit A of the Gubbi Declaration. The results of repeating Haruyuki's experiments are reported in Exhibit B of the Gubbi Declaration. It is clear from the photomicrographs presented in Exhibit A of the Gubbi Declaration that the Applicant's Osseotite® surface is not obtained when the methods of Haruyuki's examples, shown in Exhibit B, are repeated. Furthermore, the photographs in Exhibit 2 obtained from the Japanese Patent office do not resemble the surface achieved when Haruyuki's tests were repeated (Exhibit B of Gubbi Declaration), which leaves the Applicant questioning Haruyuki's methodology. Combining Krueger with Haruyuki could

not overcome the apparent difference in titanium surfaces between those of Haruyuki and the Applicant's implants.

IV. Rejections Based On Schulte

Claims 11-16, 22, 24, 25, 27-33, 36-49 and 54-56 were rejected under 35 U.S.C. § 102(b) as anticipated by the Schulte et al. 1992 article (Schulte) or as obvious under 35 U.S.C. § 103(a).

The Examiner notes that the irregularities are 2-5 microns high and substantially uniform, especially pointing to FIG. 14. The Applicants cannot agree that the only question is whether the Schulte implant is identical or substantially identical. The Schulte article contains very little information regarding titanium implants, since the main emphasis of the investigations was with aluminum oxide implants. On page 8, the authors begin to discuss the Frialit®-2 system. With regard to the surface of the titanium, they say, *"[t]he titanium surface is sandblasted and etched to achieve a relative increase in area compared to the bone . . ."* FIG. 13 shows the surface of a Frialit-2 stepped screw after blasting with aluminum oxide powder. FIG. 14 shows the surface of the stepped screw after "acid etching." It is not clear whether the surface of FIG. 14 is the result of the aluminum oxide blasting of FIG. 13 followed by acid etching. Even if it is assumed to be the case, the Schulte article is silent on the type of acid etching that was used. One skilled in the art would learn little from such as disclosure. As with Krueger, information needed to duplicate the Frialit-2 implant has been omitted. The Schulte 1992 article does not disclose enough information to make it an anticipation of the presently claimed implants, or to make the present claims obvious. It appears that the Examiner is reading more into the Schulte reference than is warranted.

The Examiner is urged to carefully review the data presented in the accompanying declaration and the above remarks and to withdraw the rejections. If further amendment is

believed to be needed, the Examiner is invited to contact the Applicant's attorney at the telephone number provided below.

The Commissioner is hereby authorized to charge deposit Account No. 10-0447 (47168-00035USC1) for any fees inadvertently omitted which may be necessary now or during the pendency of this application, except for the issue fee.

Respectfully Submitted

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